CENTER for BIOLOGICAL DIVERSITY Because life is good.

January 6, 2021

Office of Pesticide Programs
Docket number EPA-HQ-OPP-2020-0600
Environmental Protection Agency Docket Center (EPA/DC)
(28221T)
1200 Pennsylvania Ave. NW.
Washington, DC 20460-0001

**Re: Comments on EPA New Use Application – Aldicarb (Docket #: EPA-HQ-OPP-2020-0600)**

Please accept the following comments on behalf of the Center for Biological Diversity ("Center") in response to the Environmental Protection Agency's ("EPA") receipt of an application for products containing a new use of an active ingredient under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA").

The Center for Biological Diversity ("Center") is a non-profit environmental organization dedicated to the protection of native species and their habitats through science, policy, and environmental law. The Center has over 1.7 million members and online activists dedicated to the protection and restoration of endangered species and wild places. The Center has worked for twenty-six years to protect imperiled plants and wildlife, open space, air and water quality, and overall quality of life. The Center's Environmental Health Program aims to secure programmatic changes in the pesticide registration process and to stop toxic pesticides from contaminating fish and wildlife habitats. We appreciate the opportunity to provide comment.

Our organization strongly opposes any expansion in the use of the extremely hazardous pesticide aldicarb. In 2010 the EPA and Bayer reached an agreement to end the use of aldicarb in the United States after the EPA found that its ongoing use posed unacceptable dietary risks to infants and young children.[1] The crop use that resulted in the highest risk to infants and children was citrus, which Bayer agreed to cancel immediately. While the other uses of aldicarb were being phased out, AgLogic applied for, and received, approval for use on a small subset of other crops.[2]

[1] Memorandum of Agreement Between the Environmental Protection Agency and Bayer CropScience, Regarding the Registration of a Pesticide Product Containing Aldicarb. Submitted with comments.
[2] Application for New End Use Product Containing Aldicarb. Docket # EPA-HQ-OPP-2010-1021.

Alaska · Arizona · California · Minnesota · Nevada · New Mexico · New York · Oregon · Vermont · Washington, DC
P.O. Box 11374 · Portland, OR 97211-0374 tel: (503) 283.5474 fax: (503) 283.5528 www.BiologicalDiversity.org

Before the agency now is an application to expand the use of one of the most dangerous pesticide in use across citrus groves in Florida and Texas.

In a previous FIFRA "Special Local Needs" application in 2018 by AgLogic LLC to the state of Florida, AgLogic asked for support from EPA in its quest for 24(c) approval.[3] The EPA subsequently chose not to support AgLogic's application due to the agency being unable to ensure its use would be safe.[4] Now that AgLogic has applied for a FIFRA section 3 new use approval for aldicarb, the same issues remain.

While EPA did not make the Section 3 application available for this comment period (which really hampers the ability for the public to provide input), we can only assume the same issues remain. AgLogic's assertion that only 20% of the nation's citrus crop would be treated with aldicarb is unsubstantiated. Furthermore, there is absolutely no way the EPA can follow up on that claim for the decades that come. Citrus greening affects aver 90% of Florida citrus acreage.[5] With the Asian Citrus Psyllid being the primary target of the new use of aldicarb, there is absolutely no way that only a fifth of those trees will be treated. The EPA must assume that 100% of the citrus acreage in Florida and Texas will be treated.

And the argument that aldicarb is not used anywhere else, therefore it is safe to use here cannot be used as justification for approval. In fact, it's just the opposite. Aldicarb is banned in more than 100 countries,[6] one of only 36 pesticides that is classified as "extremely hazardous" by the World Health Organization,[7] and one of only 35 pesticides subject to regulation under the Rotterdam Convention,[8] an international treaty designed to reduce trade of the most hazardous chemicals in the world. Even if Mexico decides to ban aldicarb, as most of the world already has, that in no way justifies using more of it here. It's even more of a reason not to let it pollute our environment and harm people in this country.

If the EPA decides to even consider this application, which it should not, it must fully account for the full costs of aldicarb's use. There are dozens of alternative control methods[9,10] for every

---

[3] Document "3588985_1.pdf" submitted with comments
[4] Document "EPA Letter to AgLogic.pdf" submitted with comments
[5] Zhang, C. Citrus greening is killing the world's orange trees. Scientists are racing to help. Chemical Engineering News. June 9, 2019. https://cen.acs.org/biological-chemistry/biochemistry/Citrus-greening-killing-worlds-orange/97/i23#.
[6] PAN international consolidated list of banned pesticides. Submitted with comments.
[7] World Health Organization. The WHO Recommended Classification of Pesticides by Hazard and Guidelines to Classification 2009. Available here: https://apps.who.int/iris/bitstream/handle/10665/44271/9789241547963_eng.pdf?sequence=1&isAllowed=y.
[8] Annex III chemicals. Available here: http://www.pic.int/TheConvention/Chemicals/AnnexIIIChemicals.
[9] Boina D, Bloomquist J: Chemical control of the Asian citrus psyllid and of huanglongbing disease in citrus. Pest Management Science 2015, 71:808-823.

single pest that aldicarb will be used on. Even the state of Florida denied AgLogic's application for a FIFRA section 24(c) approval because company did not demonstrate that aldicarb was at least as efficacious as existing registered alternatives.[11]

The EPA must analyze the true costs of registering new uses of aldicarb as outlined in the recent 9th Circuit Court of Appeals 2020 ruling on dicamba.[12] This includes harm to the environment and humans identified in EPA's risk assessments and the economic and societal costs associated with registration – like water filtration, groundwater contamination, input costs to farmers, damage to the citrus industry's reputation/branding for using such a harmful chemical, and loss of export markets to places where no aldicarb Maximum Residue Limit (MRL) is established.

The EPA has previously identified serious human and environmental health costs from aldicarb use specifically on citrus.[13] Together with the estimated harms that EPA already identified for the currently registered uses that are in Registration Review right now[14] indicate that there is no conceivable way that aldicarb can be used in a manner that precludes a reasonable certainty of no harm.

Furthermore, if EPA believes it has identified label mitigations that reduces risk to a reasonable level, the agency must take into account how feasible those mitigations are and whether it is reasonable to assume they will be followed. The 9th Circuit Court of Appeals recently vacated EPA's registration of multiple dicamba products, in part, because the label was too complex and non-compliance was all but certain.[15] Therefore, EPA cannot simply pile restrictions onto a label without first analyzing whether those restrictions are reasonably expected to be followed.

And finally, the EPA must make any proposed decision available for public review and comment. The EPA has not even provided the application to the public for this comment period and stakeholders who are concerned about the human health and environmental implications of this decision deserve the opportunity to weigh in on the agency's analysis and decision.

If the EPA attempts to register aldicarb for use on citrus it will be in violation of FIFRA. If the agency fails to undergo ESA consultation for this new use it will also be in violation of the ESA:

---

[10] U.S. Department of Agriculture, UF/IFAS Extension Service, University of Florida, IFAS, Florida A & M University Cooperative Extension Program, and Boards of County Commissioners Cooperating. 2018–2019 Florida Citrus Production Guide: Asian Citrus Psyllid and Citrus Leafminer. Available here: https://edis.ifas.ufl.edu/in686.
[11] Document "FDACS_intent_to_deny.pdf" submitted with comments
[12] National Family Farming Coalition v. US EPA. 9th Circuit Court of Appeals opinion. Submitted with comments
[13] See document "EPA-HQ-OPP-2005-0163-0250.pdf" submitted with comment.
[14] See documents "EPA-HQ-OPP-2012-0161-0021.pdf," "EPA-HQ-OPP-2012-0161-0022.pdf," "EPA-HQ-OPP-2012-0161-0101.pdf," "EPA-HQ-OPP-2012-0161-0102.pdf."
[15] National Family Farming Coalition v. US EPA. 9th Circuit Court of Appeals opinion. Submitted with comments

**EPA must comply with duties under Section 7 of the Endangered Species Act (ESA),[16] including completion of consultation.**

As a separate, discretionary action that may affect endangered and threatened species, the EPA cannot approve new uses prior to the completion of consultations with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service ("the Services"). Without such consultation, the EPA cannot satisfy its duty to insure that its action does not jeopardize the continued existence of imperiled species across the country or adversely modify or destroy their critical habitat. Moreover, unless and until the EPA completes ESA consultation, any taking of protected species from the use of this pesticide is unlawful.

Section 7(a)(2) of the Endangered Species Act ("ESA") requires that "each federal agency *shall*, in consultation with and with the assistance of the Secretary, insure that any action authorized, funded, or carried out by such agency is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of habitat of such species which is determined by the Secretary . . . to be critical."[17] Under the Services' joint regulations implementing the ESA, the EPA is required to review its actions "at the earliest possible time" to determine whether the action may affect listed species or critical habitat.[18] Indeed, the EPA's recently finalized policy *Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes* envisions informal consultations with the Services beginning at the preliminary risk assessment stage.[19] The EPA must initiate consultation under Section 7 whenever its action "may affect" a listed species or critical habitat.[20] The phrase "may affect" has been interpreted broadly to mean that "any possible effect, whether beneficial, benign, adverse, or of an undetermined character, triggers the formal consultation requirement."[21] Accordingly, the EPA must consult with the Services on its continuing and ongoing authority over this pesticide to satisfy its duty to insure that its use will not jeopardize or adversely modify protected species or their critical habitat well *before* it proposes a registration review decision. *See* Endangered Species Act Consultation Obligations for Pesticide Approvals by the Environmental Protection Agency (enclosed).

**The EPA must consult on all synergistic and cumulative uses.** The EPA must insure that all uses of this pesticide do not jeopardize species protected by the ESA or adversely modify or destroy their critical habitat, including uses with other ingredients or other pesticides. Absent

---

[16] 16 U.S.C. § 1536.
[17] 16 U.S.C. § 1536(a)(2) (emphasis added).
[18] 50 C.F.R. § 402.14(a).
[19] http://www.epa.gov/oppfead1/cb/csb_page/updates/2013/esa-regreview.html
[20] 50 C.F.R. § 402.14(a).
[21] *Western Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 496 (9th Cir. 2011) (brackets omitted) (quoting 51 Fed. Reg. at 19,949). The threshold for triggering ESA consultation "is relatively low." *Lockyer v. U.S. Dep't of Agric.*, 575 F.3d 999, 1018 (9th Cir. 2009).

information or data to determine whether this pesticide will act synergistically with other ingredients, such uncertainty requires that the EPA decline to re-register any end use products containing more than one active ingredient and prohibit tank mixing on the labels.

At a minimum, where a product may affect listed species, all product labels must contain the following language:

> This product may have effects on federally listed threatened or endangered species or their critical habitat in some locations. When using this product, you must follow the measures contained in the Endangered Species Protection Bulletin for the county or parish in which you are applying the pesticide. To determine whether your county or parish has a Bulletin, and to obtain that Bulletin, consult *http://www.epa.gov/espp/*, or call 1-800-447-3813 no more than 6 months before using this product. Applicators must use Bulletins that are in effect in the month in which the pesticide will be applied. New Bulletins will generally be available from the above sources 6 months prior to their effective dates.[22]

**EPA must require that that the registrant provide all necessary data and studies.**

The EPA must have substantial evidence approve a new use of this pesticide. To do so, the EPA must require all necessary data and studies, including, but not limited to any previously identified data or study gaps, additional studies to evaluate effects on pollinators in accordance with the *Guidance for Assessing Pesticide Risks to Bees,*[23] information concerning estrogen or other endocrine disruption effects,[24] and any information that this pesticide or products containing this pesticide may have synergistic effects.

This is information that the EPA must require from the applicant in the first instance pursuant to 40 C.F.R. § 159.195(a), which require registrants to submit information that they reasonably should know that EPA might regard as raising concerns about the appropriate terms and conditions of registration of a product. The applicant may have information regarding synergy, whether in a U.S. Patent Application or as a result of its research and development. Failure to require any of the above information will result in the EPA underestimating adverse effects and lacking substantial evidence to support registration.

**EPA must incorporate necessary factors into evaluation and any proposed decision.**

---

[22] *Endangered Species Protection Program Field Implementation*, 70 Fed. Reg. 66392 (Nov. 2, 2005).
[23] EPA 2014. Guidance for Assessing Pesticide Risks to Bees. Available at https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf
[24] *See* 21 U.S.C. §§ 346a(d)(2)(A)(x) and 346a(p).

These factors should include the following, at a minimum:

a. effects on species listed as protected under the ESA and their critical habitat,
b. effects on pollinators and other beneficial insects, including indirect effects,
c. effects on human health or environmental safety concerning endocrine disruption, and
d. any additive, cumulative or synergistic effects of the use of this pesticide.

EPA cannot satisfy its legal duties unless it requires sufficient information and evaluates it for adverse effects before reaching any conclusions. Congress tasked the EPA with regulation of pesticides for safe use. FIFRA authorizes EPA to register a pesticide only upon determining that the pesticide "will perform its intended function without unreasonable adverse effects on the environment," and that "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."[25] The statute defines "unreasonable adverse effects on the environment" to include "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."[26] The EPA cannot meet this standard without requiring, evaluating and considering all information that causes adverse effects from the additional use of this pesticide. *Pollinator Stewardship Council v. U.S. E.P.A.*, Case No. 13-72346, Dkt. No. 58-1 at 6, 2015 WL 5255016, *1.

**EPA must place appropriate restrictions on uses to avoid and minimize adverse effects.**

The EPA has broad authority to restrict uses and place strong mitigation language on labels to avoid adverse effects and when there is uncertainty, given that the restrictions are not too complex or reasonably forseen to not be followed.

**EPA must support any assertion that the proposed new uses will actually replace older pesticide use.**

The available data show that the use of many older pesticides is actually increasing or remaining steady during the same time frame that newer pesticides or new uses are making it to market. What often happens is that newer pesticides or new uses don't always replace older ones but are used in conjunction with them, increasing the total pesticide load on the environment – a scenario that is often not calculated into the cost-benefit analysis done during the approval process. Any claims that a new pesticide approval would actually displace any pesticide use needs to be backed up by actual data, not based solely on assumption.

[25] 7 U.S.C. § 136a(c)(5)(C), (D); 40 C.F.R. § 152.112(e).
[26] 7 U.S.C. § 136(bb).

**EPA must take into account real-world scenarios.**

The EPA often claims that it is acting conservatively by using the maximum labeled use rates when estimating exposure to plants and animals. These upper-level exposure scenarios, however, do not take into account accidental spills and illegal uses of the pesticide. An assumption of 100 percent label compliance underestimates risk and is unsupported by state-collected data.[27]

A recent survey of farmers in Missouri indicated that less than half -- only 43 percent -- actually read the label each time they use pesticides.[28] Sixteen percent only read the label half the time or less and 1.2 percent have never read the label at all. Pesticide labels also have wind speed requirements that are meant to reduce drift and are used in the EPA's risk assessment process to estimate off-site exposure. Four percent of pesticide applicators never checked the wind speed before application and 40 percent of applicators checked wind speed by looking at trees, a very unreliable form of measurement that is often inaccurate.

The Centers for Disease Control and Prevention studied acute injuries related to use of fogging insect killers in residential homes.[29] While the overall injury rate was low, there were many human health harms associated with the use of these products. More importantly, the CDC measured the number of injuries before and after a mandatory label change the EPA required in 2012 to address the many incidents reported with these products. The label change, which was designed to make the products safer to use, had no effect on the number of pesticide related injuries. This indicates that some users either did not read the label instructions or failed to follow them.

Therefore, the ever-present possibility of an accidental spill indicates that this is a reasonably foreseeable event that should be accounted for when estimating peak exposure concentrations. In addition, the data that are available on label compliance indicate that it is unreasonable to assume that pesticides are always applied in accordance with the label.

**EPA must assess the enhanced toxicity of pesticide mixtures.**

---

[27] Practical Farmers of Iowa. 2013. Summary of Public Record: IDALS Pesticide Bureau Case Files for Alleged Spray Drift to Organic, Fruits and Vegetables, and Horticulture. 2008-2012. Ames, IA. Available at: http://practicalfarmers.org/app/uploads/2014/01/IDALSsummary_1-14-14NN3.pdf.

[28] Randall. July 13th, 2016. State news. *57 percent of those applying pesticides in Missouri do not read label instructions*. Available at: http://www.kttn.com/57-percent-of-those-applying-pesticides-in-missouri-do-not-read-label-instructions/.

[29] Liu R, Alarcon WA, Calvert GM, et al. Acute Illnesses and Injuries Related to Total Release Foggers — 10 States, 2007–2015. MMWR Morb Mortal Wkly Rep 2018;67:125–130. Available here: https://www.cdc.gov/mmwr/volumes/67/wr/mm6704a4.htm?s_cid=mm6704a4_w

The protocol that is currently being used to identify claims of synergy and place restrictions on pesticide use is a step above how the agency has utilized synergy data in the past, yet many steps in the process appear arbitrary and poorly executed. Therefore, we have outlined the steps that the EPA must take to ensure that its process for evaluating pesticide synergy is scientifically robust, defensible and compliant with FIFRA.

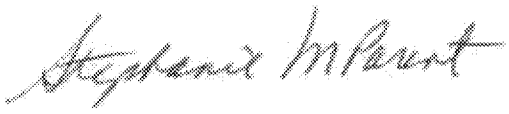
1) The EPA must request all data regarding the toxicity of mixtures containing the pesticide under consideration from the pesticide registrant/applicant, including all data on possible synergy. Pursuant to 40 CFR §159.195(a)(3), the registrant is required to submit information that indicates "[u]se of a pesticide may pose any greater risk than previously believed or reported to the Agency." Any data on chemical synergy would certainly fall into that category.

2) Before any registration decision is made, the EPA must do a comprehensive patent application and literature search for any evidence or claims that the active ingredient under consideration produces any synergistic toxicities with any chemical with which it may be co-applied.
    a) This includes patent applications or publications that find synergy with the active ingredient under consideration and any chemical that is not considered an active ingredient.
    b) This includes studies from government or any non-industry researchers and patent applications that are assigned to entities other than the pesticide registrant.
    c) This includes patent applications that have been approved, are still pending or have been denied.
    d) This includes patent applications submitted to other countries or the World Intellectual Property Organization ("WIPO").

3) The EPA should identify which patent applications or studies were analyzed for claims of synergy.
4) A synergy analysis needs to be performed for all new ingredient registrations, during significant new use registrations and during all registration reviews.
5) Tank mix prohibitions are not protective enough when evidence of synergy exists; prohibitions on "co-application in the same growing season" are needed to ensure no unreasonable adverse effects on the environment.
6) The EPA must analyze all data on pesticide synergy, including studies available from the peer-reviewed literature or state, federal or international governing body concerning the active ingredient under consideration with any ingredient it might be mixed with in a product or in the field.

Respectfully submitted,

Nathan Donley, Ph.D.
Senior Scientist
Environmental Health Program
Center for Biological Diversity



Stephanie M. Parent
Senior Attorney
Environmental Health Program
Center for Biological Diversity

# ENDANGERED SPECIES ACT CONSULTATION OBLIGATIONS FOR PESTICIDE APPROVALS BY THE ENVIRONMENTAL PROTECTION AGENCY

## I. EPA Has an Independent Duty Under the Endangered Species Act to Consult with the U.S. Fish and Wildlife Service and National Marine Fisheries Service on Pesticide Approvals.

Section 7(a)(2) of the ESA requires that "each federal agency *shall*, in consultation with and with the assistance of the Secretary, insure that any action authorized, funded, or carried out by such agency is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of habitat of such species which is determined by the Secretary… to be critical."[30] Under Section 7(a)(2), the EPA must consult with the U.S. Fish and Wildlife Service and National Marine Fisheries Service (collectively the "Services") to determine whether its actions will jeopardize listed species' survival or adversely modify designated critical habitat, and if so, to identify ways to modify the action to avoid that result.[31] The consultation requirement applies to any discretionary agency action that may affect listed species.[32] Because the EPA may decline to approve pesticides and uses, its decision represents a discretionary action that clearly falls within the ESA's consultation requirement.[33]

The EPA must initiate consultation under Section 7 whenever its action "may affect" a listed species or critical habitat.[34] Under the Services' joint regulations implementing the ESA, the EPA is required to review its actions "at the earliest possible time" to determine whether the action may affect listed species or critical habitat.[35] Indeed, the EPA's policy *Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes* envisions informal consultations with the Services beginning at the preliminary risk assessment stage.[36] The Services define "may affect" as "the appropriate conclusion when a proposed action

---

[30] 16 U.S.C. § 1536(a)(2) (emphasis added).
[31] 50 C.F.R. § 402.14.
[32] *National Association of Home Builders v. Defenders of Wildlife*, 551 U.S. 644 (2007).
[33] *See Washington Toxics Coalition v. EPA*, 413 F. 3d 1024, 1032 (9th Cir. 2005) ("even though EPA registers pesticides under FIFRA, it must also comply with the ESA when threatened or endangered species are affected.").
[34] 50 C.F.R. § 402.14(a).
[35] 50 C.F.R. § 402.14(a).
[36] U.S. Environmental Protection Agency 2013, Office of Chemical Safety and Pollution Prevention- Office of Pesticide Programs, Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes and Development of Economically and Technologically Feasible Reasonable and Prudent Alternatives, Docket ID #: EPA-HQ-OPP-2012-0442-0038 (March 19, 2013) at p. 8

may pose ***any*** effects on listed species or designated critical habitat."[37] This inquiry even includes beneficial effects. The phrase "may affect" has been interpreted broadly to mean that "any possible effect, whether beneficial, benign, adverse, or of an undetermined character, triggers the formal consultation requirement."[38] For this initial stage of review, exposure to a pesticide does not require that effects reach a pre-set level of significance or intensity to trigger the need to consult (e.g. effects do not need to trigger population-level responses). As the Services' joint consultation handbook explains, an action agency such as the EPA may make a "no effect" determination, and thus avoid undertaking informal or formal consultations, only when "the action agency determines its proposed action will not affect listed species or critical habitat."[39]

Because the use of these pesticide formulations and products "may affect" listed species and "may affect" the critical habitat of listed species, the EPA must consult with the Services regarding its pesticide approvals in order to comply with the ESA.

Fortunately the National Academy of Sciences ("NAS") has provided guidance regarding the obligations of EPA and other wildlife agencies in analyzing pesticide approvals under the ESA. The NAS committee provided a report to the EPA and Services in April of 2013 providing specific recommendations relating to the use of "best available data;" methods for evaluating sublethal, indirect, and cumulative effects; the state of the science regarding assessment of mixtures and pesticide inert ingredients; the development, application, and interpretation of results from predictive models; uncertainty factors; and what constitutes authoritative geospatial and temporal information for the assessment of individual species, habitat effects and probabilistic risk assessment methods.[40]

While the NAS report outlines areas for all three agencies to improve, the NAS report made several significant conclusions about the current ecological risk assessment process and its use of risk quotients ("RQs"), including:

---

[37] U.S. Fish and Wildlife Service and National Marine Fisheries Service 1998. *Endangered Species Consultation Handbook: Procedures for Conducting Consultation and Conference Activities Under Section 7 of the Endangered Species Act* (hereafter CONSULTATION HANDBOOK) at xvi (emphasis in original).

[38] *Western Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 496 (9th Cir. 2011) (brackets omitted) (quoting 51 Fed. Reg. at 19,949). The threshold for triggering ESA consultation "is relatively low." *Lockyer v. U.S. Dep't of Agric.*, 575 F.3d 999, 1018 (9th Cir. 2009).

[39] CONSULTATION HANDBOOK at 3-13.

[40] National Academy of Sciences 2013. *Assessing Risks to Endangered and Threatened Species from Pesticides* (hereafter NAS REPORT), Committee on Ecological Risk Assessment under FIFRA and ESA Board on Environmental Studies and Toxicology Division on Earth and Life Studies National Research Council (April 30, 2013).

- The EPA "concentration-ratio approach" for its ecological risk assessments "is ad hoc (although commonly used) and has unpredictable performance outcomes."[41]
- "RQs are not scientifically defensible for assessing the risks to listed species posed by pesticides or indeed for any application in which the desire is to base a decision on the probabilities of various possible outcomes."[42]
- "The RQ approach does not estimate risk…but rather relies on there being a large margin between a point estimate that is derived to maximize a pesticide's environmental concentration and a point estimate that is derived to minimize the concentration at which a specified adverse effect is not expected."[43]
- "Adding uncertainty factors to RQs to account for lack of data (on formulation toxicity, synergy, additivity, or any other aspect) is unwarranted because there is no way to determine whether the assumptions that are used overestimate or underestimate the probability of adverse effects."[44]

According to the NAS, the EPA concentration-ratio approach contrasts sharply with a probabilistic approach to assessing risk, which the NAS describes as "technically sound." The NAS's underlying conclusion is that EPA should move towards a probabilistic approach based on population modeling, an approach that the NMFS already utilizes.[45] The NAS also recommends that the FWS move towards a probabilistic approach in its consultations.

Following the publication of the NAS report, the agencies have developed two policy documents to guide consultations on pesticide review and approvals moving forward: (1) *Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes*,[46] and (2) *Interim Approaches for National-level Pesticide Endangered Species Act Assessments Based on Recommendations of the National Academy of Science April 2013*.[47] The agencies made clear at a November 15, 2013 public meeting that these new procedures and approaches would be "day forward" in their implementation.[48] Accordingly, approvals of pesticides and uses *must* follow these new *Interim Approaches* and comply with the requirements of the ESA.

A. Completion of Step One under Interim Approaches

---

[41] *Id.* at 107.
[42] *Id.* at 11.
[43] *Id.*
[44] *Id.*
[45] *Id.* at 107.
[46] U.S. Environmental Protection Agency 2013, Office of Chemical Safety and Pollution Prevention- Office of Pesticide Programs, Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes and Development of Economically and Technologically Feasible Reasonable and Prudent Alternatives, Docket ID #: EPA-HQ-OPP-2012-0442-0038 (March 19, 2013).
[47] Available at https://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf
[48] INTERAGENCY APPROACH FOR IMPLEMENTATION OF NATIONAL ACADEMY OF SCIENCES REPORT: ASSESSING RISKS TO ENDANGERED AND THREATENED SPECIES FROM PESTICIDES, Public Meeting Silver Spring NOAA Auditorium (Nov. 15, 2013).

As laid out in the National Academy of Sciences and *Interim Approaches* guidance, the risk assessment and consultation process should follow three steps.[49] These steps generally follow the three inquiries of the ESA consultation process: (1) the "no effect"/ "may affect" determination (2) the "not likely to adversely affect"/ "likely to adversely affect" determination (3) the jeopardy/no jeopardy and adverse modification/no adverse modification of critical habitat determination. Step One generally follows the requirements of the ESA and will in most cases identify those species at risk from pesticides that need additional review through the informal and formal consultation process. At Step One, the EPA must gather sufficient data to complete the following two related inquiries: (1) the EPA must determine whether pesticide use areas will overlap with areas where listed species are present, including whether a use area overlaps with any listed species' critical habitat (2) the EPA must determine whether off-site transport of pesticides will overlap with locations where listed species are present and/or critical habitat is designated. Off-site transport must include considerations of downstream transport due to runoff as well as downwind transport due to spray drift when the best available science indicates such transport is occurring.[50]

What the EPA should do to meet the legal requirements of the ESA is use the best available spatial data regarding the pesticide use patterns and the distribution and range of listed species to determine whether a pesticide's use overlaps with species, and then make a "may affect"/"no effect" determination. The Fish and Wildlife Service ECOS website provides GIS-based data layers for each listed species with designated critical habitat.[51] These maps are scalable and can achieve the precision needed to make accurate effects determinations regarding whether a pesticide will have "no effect" or "may affect" a listed species and are certainly accurate enough to make determinations as to whether the use of a pesticide represents adverse modification of critical habitat. Figure One provides an overlay map from ECOS of all critical habitat that has been designated for listed species thus far.

Other sources provide additional data on the distribution and life history of threatened and endangered species. NatureServe provides detailed life history information, including spatial distribution, for native species across the United States.[52] In addition, many State governments

---

[49] NAS REPORT at 37-38.

[50] The Center acknowledges that in many areas, atmospheric transport is difficult to model and assess. However, in some areas, the impacts of atmospheric transport of pesticides are well understood. A recent study found that a variety of pesticides are accumulating in the Pacific chorus frogs (*Pseudacris regilla*) through atmospheric deposition at remote, high-elevation locations in the Sierra Nevada mountains, including in Giant Sequoia National Monument, Lassen Volcanic National Park, and Yosemite National Park Smalling, K.L., et al. 2013. *Accumulation of Pesticides in Pacific Chorus Frogs (Pseudacris regilla) from California's Sierra Nevada Mountains*, Environmental Toxicology and Chemistry, 32:2026–2034.

[51] US Fish and Wildlife Service Environmental Conservation Online System. http://ecos.fws.gov

[52] NatureServe Get data. http://www.natureserve.org/getData/index.jsp

collect detailed information on non-game species through their State Wildlife Action Plans.[53] In short, there are many sources of data that can provide EPA with the detailed information it needs to conduct an effects determination for each species. If there is a subset of species where it believes information is still lacking, EPA should make that clear to all stakeholders which species specifically it believes such data are lacking early in the process such that this information can be collected from the Services and other sources.

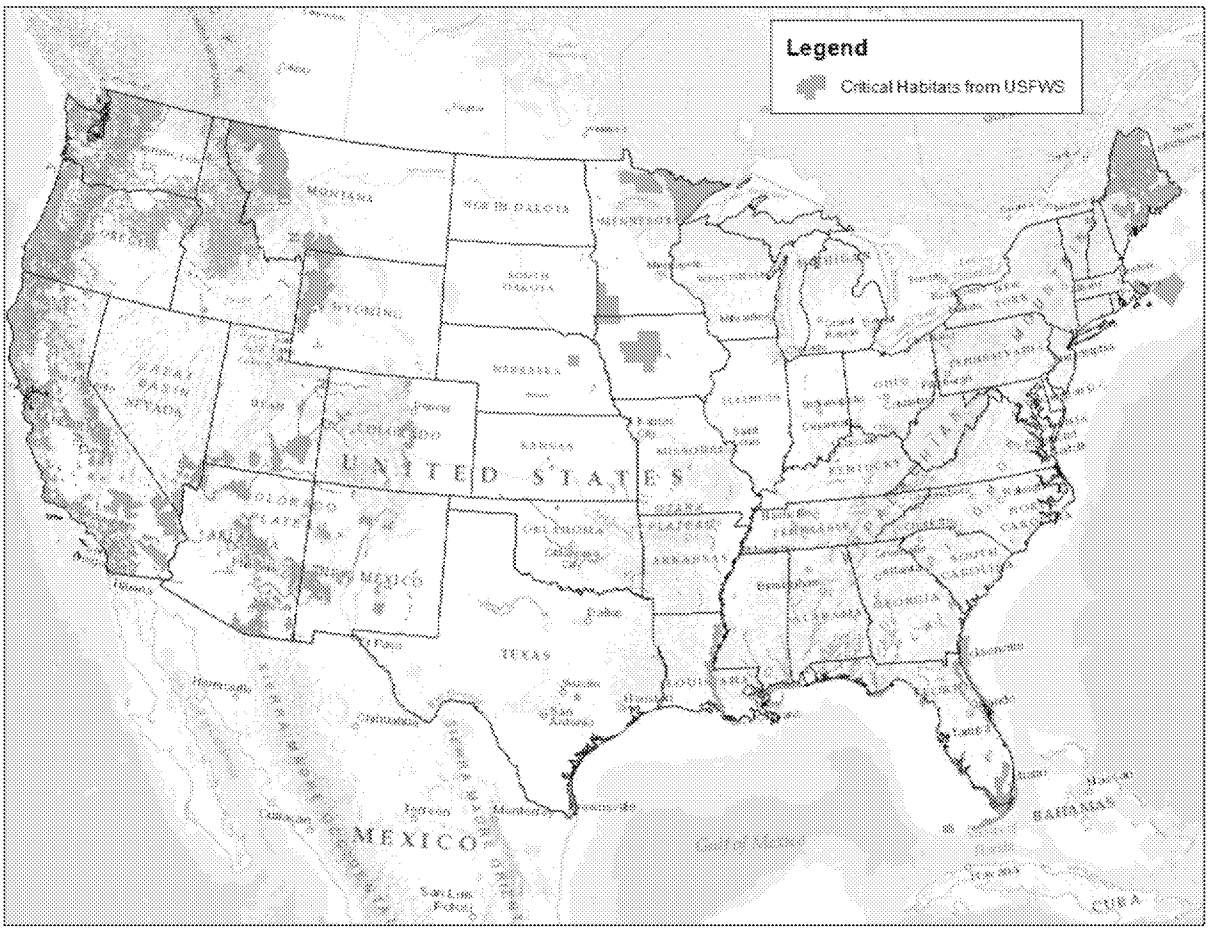
///

///

///

[53] State Wildlife Action Plans. http://teaming.com/state-wildlife-action-plans-swaps

**Figure One – Base Composite Map of Critical Habitat in the United States**[54]




To make scientifically valid effects determinations, EPA will also need the best available spatial data regarding the use of pesticides. The U.S. Department of Agriculture and the U.S. Geological Survey[55] collect data on an enormous suite of pesticide active ingredients each year, as do several private organizations. Thus, it should be possible to determine where areas of geographic overlap between species and pesticide usage occur. If empirical data on pesticide use or persistence in the environment is lacking geospatial modeling can be used to determine where pesticide use may overlap with affected endangered species.

With the completion of the problem formulations for Ecological Risk, the EPA should now move quickly to begin the informal consultation process for pesticides, starting with a spatial analysis as envisioned as Step one. If this information is collected and assessed properly, then it should then be relatively straightforward for the EPA to begin to develop geographic restriction on the

[54] US Fish and Wildlife Service Environmental Conservation Online System. http://ecos.fws.gov
[55] USGS, National Water-Quality Assessment (NAWQA) Program, Pesticide National Synthesis Project, Annual Pesticide Use Maps: 1992-2013, available at https://water.usgs.gov/nawqa/pnsp/usage/maps/

use of pesticides wherever designated critical habitat for a listed species exists as parts of Step Two and Step Three. However, because not all threatened and endangered species have critical habitat, the EPA will also have to collect data on the distribution and range of species that do not yet have critical habitat to determine whether the use of these pesticides will jeopardize any of those species.

B. Label Requirements.

FIFRA requires that the EPA evaluate and reregister a pesticide every 15 years. During that 15 year period, crop distributions change, use patterns for pesticides change, and listed species change. By the time the registration review process is complete several years from now, additional species will almost certainly be protected by the ESA. Of the species currently listed, some may move towards recovery and become more common while others may become even more imperiled.

Product labels must be able to adapt to changing conditions on the ground to ensure that the use of these pesticides do not cause unanticipated adverse impacts that result in levels of take not authorized through the Section 7 consultation process. Fortunately, the EPA has already developed a system that can address impacts to endangered species and that provides for geographically-targeted conservation measures on the ground through its *Bulletins Live! Two* website.[56] The Center recommends that whenever a pesticide may affect listed species, both as a precautionary matter and as a mechanism to implement any conservation measures that are implemented in the informal and formal consultation process, the EPA use the *Bulletins Live! Two* system to incorporate these measures. Accordingly, all product labels for pesticides affecting endangered species must contain the following language:

> This product may have effects on federally listed threatened or endangered species or their critical habitat in some locations. When using this product, you must follow the measures contained in the Endangered Species Protection Bulletin for the county or parish in which you are applying the pesticide. To determine whether your county or parish has a Bulletin, and to obtain that Bulletin, consult *http://www.epa.gov/espp/*, or call 1-800-447-3813 no more than 6 months before using this product. Applicators must use Bulletins that are in effect in the month in which the pesticide will be applied. New Bulletins will generally be available from the above sources 6 months prior to their effective dates.[57]

---

[56] U.S. Environmental Protection Agency Endangered Species Protection Bulletins. http://www.epa.gov/espp/bulletins.htm

[57] *Endangered Species Protection Program Field Implementation*, 70 Fed. Reg. 66392 (Nov. 2, 2005).

## II. The EPA Must Make Defensible "Not Likely to Adversely Affect" and "Likely to Adversely Affect" Determinations as a Prerequisite for Defensible "Jeopardy" and "No Jeopardy" Determinations.

At the informal consultation stage, the EPA must determine whether the use of a pesticide is either "not likely to adversely affect" ("NLAA") a listed species or is "likely to adversely affect" ("LAA") a listed species.[58] The Services define NLAA as "when effects on listed species are expected to be discountable, insignificant, or completely beneficial." Discountable effects are those that are extremely unlikely to occur and that the Services would not be able to meaningfully measure, detect, or evaluate" because of their insignificance[59] In the context of pesticides, only if predicted negative effects are discountable or insignificant can the EPA avoid the need to enter formal consultations with the Services. This is *not* a high threshold. The EPA is not required to make a determination as to whether exposure to a pesticide results in population level changes in order to request formal consultations. The Center believes that the Step Two approach described is generally compatible with the mandates of the ESA regarding actions that may affect listed species. The one in a million mortality threshold for "likely to adversely affect" reflects the ESA's and the Consultation Handbook's requirements. The decision to consider 1) sublethal effects to species, 2) additive, synergistic and cumulative effects of all chemicals and non-chemical stressors present in the pesticide formulation, tank mixture, and the environment, 3) and the fate and action of pesticide degradates at Step Two is also consistent with the ESA's requirements and represents an important change from the previous EPA approach, in which the EPA was making policy judgments at Step Two as to whether known, adverse, population-level impacts crossed a severity threshold to warrant consultations.

Finally, the Center notes that at Step Three, the formal consultation process, the EPA and Services must consider the environmental baseline as well as all cumulative effects when determining if the approval pesticides, formulations, or uses will jeopardize any threatened or endangered species. The Services define environmental baseline as "the past and present impacts of all Federal, State, or private actions and other human activities in an action area, the anticipated impacts of all proposed Federal projects in an action area that have already undergone formal or early section 7 consultation, and the impact of State or private actions that are contemporaneous with the consultation in process."[60] Cumulative effects are defined as "those effects of future State or private activities, not involving Federal activities, that are reasonably certain to occur within the action area of the Federal action subject to consultation."[61]

---

[58] U.S. Fish and Wildlife Service and National Marine Fisheries Service. 1998. *Endangered Species Consultation Handbook: Procedures for Conducting Consultation and Conference Activities Under Section 7 of the Endangered Species Act*. at 3-1.
[59] *Id*. at xv.
[60] *Id*. at xiv.
[61] *Id*. at xiii.

Pesticide consultations must consider the interactions between the active ingredient under review and other pollutants in the present in the environment.

The Food Quality Protection Act of 1996 ("FQPA") requires EPA to measure risk of a pesticide based on "… available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity." The EPA has interpreted this to mean that only pesticides with a common mechanism of action be assessed in a cumulative risk assessment. We strongly disagree with this interpretation. First, the term "other substances" can include chemicals other than pesticides and also stressors that are not chemicals, like radiation and climate change. The EPA itself defines cumulative risk as "the combined risks from aggregate exposures to multiple agents or stressors," where agents or stressors can be chemicals or "may also be biological or physical agents or an activity that, directly or indirectly, alters or causes the loss of a necessity such as habitat."[62] Second, the term "common mechanism of toxicity" does not dictate that the EPA only consider agents or stressors with a common mechanism of action. The National Research Council has recommended that the EPA use the endpoint of common adverse outcome rather than common mechanism of action to group agents that could act cumulatively.[63] As for how this relates to EPA's duty under the ESA, cumulative risk in the ESA needs to be interpreted very broadly as this piece of legislation is a precautionary document meant to ensure that no harm comes to listed species. Although the EPA interprets the scope of cumulative risk assessments under FQPA to be limited to the common mechanism effect, **there is absolutely no such written or intended limit in the ESA**. The EPA needs to begin discussions on how it will test true cumulative risk, the way it is broadly defined in the ESA, because current metrics and protocols that measure cumulative risk under FQPA are inadequate for the EPA to meet its legal obligations under the ESA.

Pesticide and their residues and degradates do not occur in single exposure situations and many different mixtures of pesticides occur in water bodies at the same time.[64] The mixtures of these chemicals can combine to have additive or synergistic effects that are substantially more dangerous and increase the toxicity to wildlife.[65] Thus, to fully understand the ecological effects and adverse impacts, the EPA and the Services must consider the pesticide's use in the context of *current* water quality conditions nationwide. In particular, the use of pesticides in watersheds

---

[62]U.S. Environmental Protection Agency 2003. Framework for Cumulative Risk Assessment. U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment, Washington Office, Washington, DC, EPA/600/P-02/001F, 2003. Pg. xvii.

[63] National Research Council (US) Committee on the Health Risks of Phthalates. Phthalates and Cumulative Risk Assessment: The Tasks Ahead. Washington (DC): National Academies Press (US); 2008. Page 4.

[64] NMFS 2011, *Endangered Species Act Section 7 Consultation Draft Biological Opinion for the Environmental Protection Agency's Pesticide General Permit for Discharges from the Application of Pesticides* (hereafter Draft BiOp) at 118-119, lines 4209-31; Gilliom, R.J. et al. 2006. *Pesticides in the Nation's Streams and Ground Water, 1992–2001—A Summary*, available at http://pubs.usgs.gov/fs/2006/3028/.

[65] Draft BiOp at 127-129, lines 4471-4515; Gilliom, R.J. 2007. *Pesticides in the Nation's Streams and Ground Water*; Environmental Science and Technology, 413408–3414.

that contain threatened or endangered species and where water quality is already impaired could be particularly problematic. Therefore, the agencies must use the best available data to fully inform its ecological risk assessment by considering water quality.

In conclusion, the EPA should move quickly to assemble the needed spatial data to make an informed "no effect" or "may affect" finding for *each* listed species that will likely overlap with the use of these pesticides or come into contact with its environmental degradates. If there is overlap, EPA must at a minimum conclude that the use of these pesticides "may affect" listed species. Where this occurs, EPA has a choice—(1) the EPA can elect to complete an informal consultation through a biological assessment (also known as a biological evaluation), or (2) the EPA can undergo formal consultation with the Services. If EPA completes a biological assessment and implements geographically-tailored conservation measures through *Bulletins Live! Two*, it may be able to reach NLAA determinations via the informal consultation process and alleviate the need for formal consultations. In the alternative, the EPA can move directly to formal consultation after making "may affect" determinations for species where the impacts of pesticides are more complex and will take additional expertise to develop sufficient conservation measures. Cumulative effects need to be measured in Steps 2 and 3.

## III. EPA and the Services Must Assess the Adverse Impacts on Critical Habitat.

Section 7 of the ESA prohibits agency actions that would result in the "destruction or adverse modification of [critical] habitat."[66] This inquiry is separate and distinct from the question as to whether a pesticide approval will result in jeopardy to any listed species. A no jeopardy finding (or a Not Likely to Adversely Affect finding in an informal consultation) is *not* equivalent to a finding that critical habitat will not be adversely modified. While there is much overlap between these two categories (for example, as in *Tennessee Valley Authority v. Hill*[67] where the proposed agency action to build a dam would both destroy a species' habitat and kill individual members of the species in the same time) many agency actions do result in adverse modification to critical habitat without causing direct harms to species that do rise to the level of jeopardy.[68] Indeed, the ESA's prohibition on "destruction or adverse modification" of critical habitat does not contain any qualifying language suggesting that a certain species-viability threshold must be reached prior to the habitat modification prohibition coming into force.

As three federal circuit courts have made abundantly clear, avoiding a species' immediate extinction is not the same as bringing about its recovery to the point where listing is no longer necessary to safeguard the species from ongoing and future threats. Therefore, Section 7

---

[66] 16 U.S.C. § 1536(a)(2).
[67] 437 U.S. 153 (1978)
[68] *See* Owen, D. 2012. *Critical Habitat and the Challenge of Regulating Small Harms*. Florida Law Review 64:141-199.

requires that critical habitat not be adversely modified in ways that would hamper the *recovery* of listed species.[69] These potent pesticides with known adverse ecological effects have the potential to adversely modify critical habitat by altering ecological community structures, impacting the prey base for listed species, and by other changes to the physical and biological features of critical habitat. Accordingly, the informal consultation must separately evaluate whether these pesticide products and formulations will adversely modify critical habitat regardless of whether these pesticide products jeopardize a particular listed species. For example, if plant communities alongside a water body that has been designated as critical habitat suffer increased mortality, and this then results in increased temperatures or increased sedimentation, that would represent adverse modification of critical habitat. Likewise, if pesticides are toxic to species lower in the food chain, and a threatened or endangered species feeds on those affected prey species, this impact to the food web would represent a clear example of adverse modification to critical habitat.

EPA's evaluation must address impacts to critical habitat even if the direct effects on listed species fall below the NLAA or jeopardy thresholds. The Center recommends that the EPA design conservation measures—and implement those measures using *Bulletins Live! Two* — specifically to protect critical habitat of listed species from exposure to pesticides, and where appropriate, prohibit its use altogether in critical habitat where necessary. Doing so would provide meaningful, on-the-ground protections for hundreds of listed species, and may in some cases, help the EPA and the Services then reach a defensible NLAA or "no jeopardy" opinion.

## IV. EPA Has an Independent Duty Under the Endangered Species Act to Consult with the U.S. Fish and Wildlife Service and National Marine Fisheries Service on the Approval of All End-use Product Labels.

Just as the EPA must consult with the Services regarding the reregistration of an active pesticide ingredient, EPA must also consult with the Services regarding the registration or approval of end use and technical pesticide products. Such consultations must also occur at the earliest possible time to ensure that specific product formulations do not result in jeopardy for a listed species or adversely modify critical habitat.

In addition, because end use formulations may result in mixes of the active ingredient with "other ingredients" before application, the EPA must consider during the consultation process the effects of these "inert" or "other" ingredients together with the active ingredient on listed species and set appropriate conservation restrictions accordingly. As noted in *Washington Toxics Coalition v. U.S. Dept. of Interior*, "other ingredients" within a pesticide end product may

[69] *See Gifford Pinchot Task Force v. FWS*, 378 F.3d 1059, 1069-71 (9th Cir. 2004) (finding a FWS regulation conflating the requirements of survival and recovery to be unlawful); *see also N.M. Cattle Growers Ass'n v. FWS*, 248 F.3d 1277, 1283 n.2 (10th Cir. 2001); *Sierra Club v. FWS*, 245 F.3d 434, 441-42 (5th Cir. 2001)

cause negative impact to listed species even if they are less toxic than the active ingredient being reviewed.[70] "Other ingredients," such as emulsifiers, surfactants, anti-foaming ingredients, and fillers may harm listed species and adversely modify critical habitat. Many of the more than 4,000 potentially hazardous additives allowed for use as pesticide additives are environmental contaminants and toxins that are known neurotoxins and carcinogens.[71] The EPA has routinely failed to consult with the Services on the registration of "other ingredients," potentially compounding harms to listed species by allowing such ingredients to be introduced widely into the environment. EPA must, as part of the consultation process, consider the range of potential impacts by using different concentrations and different formulations of the active ingredient, as well as the potential negative impacts of "other ingredients" used in end use products.

The National Academy of Science report recognized that without real-world considerations of where listed species are located, the relative conservation status of listed species, the environmental baseline, and the interaction of pesticides with other active ingredients, pesticide degradates, and other pollutants, the EPA risk assessment process will not be able to make meaningful predictions about which endangered species will be adversely affected. Until the EPA can conduct realistic assessments, it should take a precautionary approach and enter into formal consultations with the Services as outlined in the *Interim Approaches* document.

[70] 457 F. Supp. 2d 1158 (W.D. Wash 2006).
[71] Draft BiOp at 113, lines 4062-68; 120-121, lines 4262-308; 127, lines 4445-4455; Northwest Coalition for Alternatives to Pesticides, et al., Petition to Require Disclosure of Hazardous Inert Ingredients on Pesticide Product Labels. 2006. http://www.epa.gov/opprd001/inerts/petition_ncap.pdf.